

Please type a plus sign (+) inside this box → ☐

PTO/SB/08B (08-00)
Approved for use through 10/31/2002. OMB 0651-0031
U. S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.



Substitute for form 1449B/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 1

Complete if Known

Application Number	09/954,695
Filing Date	September 11, 2001
First Named Inventor	CUNNINGHAM et al.
Group Art Unit	1634
Examiner Name	Goldberg, J.
Attorney Docket Number	GP116-02.UT

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS

Examiner Initials ¹	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
JP		CAI et al., "C. parvum ribosomal RNA gene for 18S rRNA (pCPA911)", DATABASE NCBI 'Onlinel, June 1993, Accession No. X64340	
		CAI et al., "PCR cloning and nucleotide sequence determination of the 18S rRNA genes and internal transcribed spacer 1 of the protozoan parasites Cryptosporidium parvum and Cryptosporidium muris", Biochim Biophys Acta., July 1992, 1131(3):317-20	
		DEERE et al., "Evaluation of fluorochromes for flow cytometric detection of Cryptosporidium parvum oocysts labelled by fluorescent in situ hybridization", Lett Appl Microbiol., Dec. 1998, 27(6):352-6	
		DENG et al., "Immunomagnetic Capture PCR To Detect Viable Cryptosporidium parvum Oocysts from Environmental Samples", Appl Environ Microbiol., Aug. 1997, 63(8):3134-8	
		HALLIER-SOULIER et al., "An immunomagnetic separation polymerase chain reaction assay for rapid and ultra-sensitive detection of Cryptosporidium parvum in drinking water", FEMS Microbiol Lett., July 1999, 176(2):285-9	
		LABERGE et al., "Detection of Cryptosporidium parvum in Raw Milk by PCR and Oligonucleotide Probe Hybridization", Appl Environ Microbiol., Sept. 1996, 62(9):3259-64	
		LINDQUIST, "Probes for the Specific Detection of Cryptosporidium parvum", Wat Res., 1997, 31(10):2668-71	
		PIENIAZEK et al., "Cryptosporidium parvum 18S ribosomal RNA gene, complete", DATABASE NCBI 'Onlinel, March 1996, Accession No. L16996	
✓		WANG et al., "Electrochemical biosensor for detecting DNA sequences from the pathogenic protozoan Cryptosporidium parvum", Talanta, 1997, 44:2003-2010	

Examiner Signature

J. Goldberg

Date

Considered

6/24/03

¹EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Please type a plus sign (+) inside this box ☐

Approved for use through 10/31/2002. OMB 0651-003
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 4

Complete if Known

Application Number 09/954,695
Filing Date September 11, 2001
First Named Inventor CUNNINGHAM et al.
Group Art Unit To be assigned 1b34
Examiner Name To be assigned Goldberg
Attorney Docket Number GP116-02.UT

U.S. PATENT DOCUMENTS

Examiner Initials ¹	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
↓		4851330	A	Kohne	07-25-1989	
		5030557	A	Hogan et al.	07-09-1991	
		5399491	A	Kacian et al.	03-21-1995	
		5539082	A	Nielsen et al.	07-23-1996	
		5556774	A	Wiedenmann et al.	09-17-1996	
		5591434	A	Jenkins et al.	01-07-1997	
		5690825	A	Parton	11-25-1997	
		5693472	A	Steele et al.	12-02-1997	
		5770368	A	De Leon et al.	06-23-1998	
		5789190	A	Crabb et al.	08-04-1998	
		5820767	A	Kane et al.	10-13-1998	
		5840488	A	Hogan	11-24-1998	
		5925517	A	Tyagi et al.	07-20-1999	
		6054279	A	Nadeau et al.	04-25-2000	
		6130038	A	Becker et al.	10-10-2000	
		6146838	A	Williams et al.	11-14-2000	

FOREIGN PATENT DOCUMENTS

Examiner Initials ¹	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	To
		Office ³	Number ⁴	Kind Code ⁵ (if known)				
↓		EP	0652974	B1	Minister of Agr., Fisheries & Food of the U.K.	05-17-1995		
		WO	9402635	A1	Minister of Agr., Fisheries & Food of the U.K.	02-03-1994		
		WO	9404681	A1	Istituto Superiore Di Sanita et al.	03-03-1994		
		WO	9634978	A1	MacQuarie Research Limited et al.	11-07-1996		
		WO	9640926	A2	The Board of Regents of the University of Oklahoma	12-19-1996		
		WO	9702281	A1	Murdoch University	01-23-1997		
		WO	9703362	A1	ImmuCell Corporation	01-30-1997		
		WO	9708204	A1	MacQuarie Research Ltd et al.	03-06-1997		
		WO	9742349	A1	Metropolitan Water District of Southern California	11-13-1997		
		WO	9804675	A2	Pall Corporation	02-05-1998		

Examiner
Signature

J. Goldberg

Date

Considered

6/24/03

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

RECEIVED

JAN 29 2002



PTO/SB/08A (08/01)

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Complete if Known

Application Number	09/954,695
Filing Date	September 11, 2001
First Named Inventor	CUNNINGHAM et al.
Group Art Unit	To be assigned 1634
Examiner Name	To be assigned Gailberg
Attorney Docket Number	GP116-02.UT

(use as many sheets as necessary)

Sheet	2	of	4
-------	---	----	---

Attorney Docket Number	GP116-02.UT
------------------------	-------------

[illegible][illegible]

J. Goldberg

6/24/03

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO:** Assistant Commissioner for Patents, Washington, DC 20231.

Please type a plus sign (+) inside this box → ☐

PTO/SB/089 (08-00)
Approved for use through 10/31/2002. OMB 0651-0031
U. S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet **3** of **4**

Compl. to if Known

Application Number	09/954,695
Filing Date	September 11, 2001
First Named Inventor	CUNNINGHAM et al.
Group Art Unit	To be assigned 1634
Examiner Name	To be assigned Goldberg
Attorney Docket Number	GP116-02.UT

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials ¹	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
g		AWAD-EL-KARIEM et al., "Detection and species identification of Cryptosporidium oocysts using a system based on PCR and endonuclease restriction", Parasitology, July 1994, p. 19-22, vol. 109, Cambridge University Press, UK	
		BALATBAT et al., "Detection of Cryptosporidium parvum DNA in Human Feces by Nested PCR", J. Clin. Microbiol., July 1996, p. 1769-1772, vol. 34, no. 7, American Society of Microbiology, US	
		CARRAWAY et al., "Genetic Markers Differentiate C. parvum Isolates", J. Eukaryot. Microbiol., Sept.-Oct. 1994, p. 26S, vol. 41, no. 5, Allen Press Inc., US	
		CHRISP et al., "Similarities and differences between DNA of cryptosporidium parvum and C. wrairi detected by the polymerase chain reaction", Folia Parasitol., 1994, p. 97-100, vol. 41, no. 2, Czech Academy of Sciences, CZ	
		DEERE et al., "Rapid method for fluorescent in situ ribosomal rna labeling of cryptosporidium parvum", J. Appl. Microbiol., Nov. 1998, p. 807-818, vol. 85, no. 5, Blackwell Science Limited, UK	
		GARCIA et al., "Detection of Microsporidial Spores in Fecal Specimens from Patients Diagnosed with Cryptosporidiosis", J. Clin. Microbiol., July 1994, p. 1739-1741, vol. 32, no. 7, American Society of Microbiology, US	
		KILANI et al., "Geographical Variation in 18S rRNA Gene Sequence of Cryptosporidium Parvum", Int. J. Parasitol., April 1994, p. 303-306, vol. 24, no. 2, Elsevier Science Limited, UK	
		LAXER et al., "DNA Sequences for the Specific Detection of Cryptosporidium Parvum by the Polymerase Chain Reaction" Am. J. Trop. Med. Hyg., Dec. 1991, p. 688-694, vol. 45, no. 6, Allen Press Incorporated, US	
		LINDQUIST et al., "Criteria for evaluation of proposed protozoan detection methods", J. Microbiol. Methods, July 1999, p. 33-43, vol. 37, no. 1, Elsevier Science Publishers BV, NE	
		LONG et al., "The Diagnosis of Old and New Gastrointestinal Parasites", Clin. Lab. Med., June 1995, p. 307-331, vol. 15, no. 2, W B Saunders Company, US	
		MARSH et al., "Sequence Analysis and Comparison of Ribosomal DNA From Bovine Neospora to Similar Coccidial Parasites", J. Parasitol., Aug. 1995, p. 530-535, vol. 81, no. 4, American Society of Parasitologists, US	
↓		MORGAN et al., "Differentiation Between Human and Animal Isolates of Cryptosporidium Parvum Using rDNA Sequencing and Direct PCR Analysis", J. Parasitol., Oct. 1997, p. 825-830, vol. 83, no. 5, American Society of Parasitologists, US	

Examiner Signature

J. Goldberg

Date Considered

6/24/03

¹EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

² Unique citation designation number. ³ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.



RECEIVED
JAN 29 2002
TECHNICAL CENTER 1600 2ND ST

RECEIVED

Please type a plus sign (+) inside this box → ☐

PTO/SB/08B (08-00)

Approved for use through 10/31/2002. OMB 0654-0031

U. S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet **4** of **4**

Complete if Known

Application Number **09/954,695**
 Filing Date **September 11, 2001**
 First Named Inventor **CUNNINGHAM et al.**
 Group Art Unit **To be assigned 1634**
 Examiner Name **To be assigned Goldberg**
 Attorney Docket Number **GP116-02.UT**

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
<i>JS</i>		MORGAN et al., "Phylogenetic Analysis of Cryptosporidium Isolates from Captive Reptiles Using 18S rDNA Sequence Data and Random Amplified Polymorphic DNA Analysis", J. Parasitol., June 1999, p. 525-530, vol. 85, no. 3, American Society of Parasitologists, US	
		ROCHELLE et al., "Development of a Rapid Detection Procedure for Cryptosporidium, Using In Vitro Cell Culture Combined with PCR", J. Eukaryot. Microbiol., Sept.-Oct. 1996, p. 72S, vol. 43, no.5, Allen Press, Inc., US	
		SHEPHERD et al., "An Evaluation of Methods for the Simultaneous Detection of Cryptosporidium Oocysts and Giardia Cysts from Water", Appl. Environ. Microbiol., Apr. 1996, p. 1317-1322, vol. 62, no. 4, American Society for Microbiology, US	
		SINGH, "Molecular Methods for Diagnosis and Epidemiological Studies of Parasitic Infections", Int. J. Parasitol., Oct. 1997, p. 1135-1145, vol. 27, no. 10, Elsevier Science Limited, UK	
		SLIFKO et al., "An In Vitro Method for Detecting Infectious Cryptosporidium Oocysts with Cell Culture", Appl. Environ. Microbiol., Sept. 1997, p. 3669-3675, vol. 63, no. 9, American Society for Microbiology, US	
		VESEY et al., "The use of a ribosomal RNA targeted oligonucleotide probe for fluorescent labelling of viable Cryptosporidium parvum oocysts", J. Appl. Microbiol., Sept. 1998, p. 429-440, vol. 85, no. 3, Blackwell Science Limited, UK	
		WEBSTER et al., "Detection of Cryptosporidium parvum using a specific polymerase chain reaction" Vet. Parasitol., Oct. 1993, p. 35-44, vol. 50, no. 1-2, Elsevier Science Publishers BV, NE	
		WEBSTER et al., "Detection of Cryptosporidium parvum oocysts in faeces: comparison of conventional coproscopical methods and the polymerase chain reaction", Vet. Parasitol., Jan. 1996, p. 5-13, vol. 61, no. 1-2, Elsevier Science Publishers BV, NE	
		XIAO et al., "Phylogenetic Analysis of Cryptosporidium Parasites Based on the Small-Subunit rRNA Gene Locus", Appl. Environ. Microbiol., Apr. 1999, p. 1578-1583, vol. 65, no. 4, American Society for Microbiology, US	
<i>↓</i>		ZHU et al., "Direct Isolation of DNA from Patient Stools for Polymerase Chain Reaction Detection of Cryptosporidium parvum", J. Infect. Dis., May 1998, p. 1443-1446, vol. 177, no. 5, University of Chicago Press, US	

Examiner Signature

G. Goldberg

Date Considered

6/24/03

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

U.S. PATENT & TRADEMARK OFFICE
 JAN 25 2002
 J192

RECEIVED
 JAN 29 2002